CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-281

ADMINISTRATIVE DOCUMENTS

13.0 Patent Information

We, TAP Pharmaceutical Products Inc. (TAP), certify that the drug, lansoprazole, is claimed in U.S. Patents as listed below. [redacted] has licensed lansoprazole as covered by these patents to TAP.

U.S. Patent No.	Expiration Date	Coverage
4,628,098	05/10/09	Compound
4,689,333	07/29/05	Pharmaceutical formulations containing lansoprazole, and a method of treating gastritis
5,013,743	02/12/10	Use of lansoprazole for combating diseases caused by the genus *Campylobacter*
5,026,560	06/25/08	Formulation (spherical granules)
5,045,321	09/03/08	Formulation (spherical granules or tablets stabilized with inorganic salt)
5,093,132	09/03/08	Formulation stabilized with inorganic salt
5,433,959	09/03/08	Stabilized pharmaceutical composition

MAY - 3 2001

EXCLUSIVITY SUMMARY for original NDA # 21-281

Trade Name PREVACID® for Delayed-Release Oral Suspension

Generic Name (lansoprazole)

Applicant Name TAP Pharmaceutical Products, Inc. **HFD-180**

Approval Date May 3, 2001

PART I: IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "YES" to one or more of the following questions about the submission.

   a) Is it an original NDA? YES ✓ NO __

   b) Is it an effectiveness supplement? YES __ NO ✓
   If yes, what type(SE1, SE2, etc.)?

   c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "NO.")

   YES __ NO ✓

   If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

   The NDA is supported by 2 studies to demonstrate bioequivalence between the PREVACID (lansoprazole) for Delayed-Release Oral Suspension and PREVACID (lansoprazole) Delayed-Release Capsules. No clinical studies were conducted.

   If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

   N/A

   d) Did the applicant request exclusivity? YES __ NO ✓

   If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

   N/A

   e) Has pediatric exclusivity been granted for this Active Moiety?

   YES __ NO ✓

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use? (Rx to OTC) Switches should be answered No).

YES __ NO ✓

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

3. Is this drug product or indication a DESI upgrade? YES __ NO ✓

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9 (even if a study was required for the upgrade).

PART II: FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2, as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES ✓ NO __

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA #20-406, Prevacid (lansoprazole) Delayed-Release Capsules

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9. IF "YES," GO TO PART III.

PART III: THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS
To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2, was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES __ NO ✓

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

For the purposes of this section, studies comparing two products with the same ingredient(s) are considered to be bioavailability studies.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /___/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval **AND GO DIRECTLY TO SIGNATURE BLOCK ON Page 9:**

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /___/ NO /___/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /___/

If yes, explain: _____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /___/

If yes, explain: _____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Investigation #1, Study # _____
Investigation #2, Study # _____
Investigation #3, Study # _____

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

(a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1	YES /___/	NO /___/
Investigation #2	YES /___/	NO /___/
Investigation #3	YES /___/	NO /___/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

NDA # _____ Study # _____
NDA # _____ Study # _____
NDA # _____ Study # _____

(b) For each investigation identified as "essential to the approval," does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1	YES /___/	NO /___/
Investigation #2	YES /___/	NO /___/
Investigation #3	YES /___/	NO /___/

If you have answered "yes" for one or more investigations, identify the NDA in which a similar investigation was relied on:

NDA # _____ Study # _____
NDA # _____ Study # _____
NDA # _____ Study # _____

(c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Investigation #_, Study # _____
Investigation #_, Study # _____
Investigation #_, Study # _____

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

(a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1

IND # ___ YES /___/ NO /___/ Explain: ___

Investigation #2

IND # ___ YES /___/ NO /___/ Explain: ___

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1
YES /___/ Explain _____ NO /___/ Explain _____

Investigation #2

YES /___/ Explain _____ NO /___/ Explain _____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

{See appended electronic signature page}
Preparer: Cheryl Perry
Regulatory Health Project Manager

{See appended electronic signature page}
Division Director: Lilia Talarico

Form OGD-011347
Revised 8/7/95; edited 8/8/95; revised 8/25/98, edited 3/6/00

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Lilia Talarico
5/3/01 05:29:03 PM

FDA Links Searches Check Lists Tracking Links Calendars Reports Help

MAY - 3 2001

PEDIATRIC PAGE (Complete for all original application and all efficacy supplements)

View as Word Document

NDA Number:	021281	**Trade Name:**	LANSOPRAZOLE FOR SUSPENSION
Supplement Number:	000	**Generic Name:**	LANSOPRAZOLE FOR SUSPENSION
Supplement Type:	N	**Dosage Form:**	
Regulatory Action:	OP	**COMIS Indication:**	SHORT TERM TREATMENT FOR HEALING/SYMPTOM RELIEF OF ESOPHAGITIS EROSIVE
Action Date:	7/3/00		

Indication # 1: Short-term treatment of active duodenal ulcer, H. pylori eradication to reduce the risk of duodenal ulcer recurrence, maintenance of healed duodenal ulcers, short-term treatment of active benign gastric ulcer, healing of NSAID-associated gastric ulcer, risk reduction of NSAID-associated gastric ulcer, short-term treatment of symptomatic gastroesophageal reflux disease (GERD), short-term treatment of erosive esophagitis, maintenance of healing of erosive esophagitis, and pathological hypersecretory conditions including Zollinger-Ellison syndrome.

Label Adequacy: Inadequate for ALL pediatric age groups

Formulation Needed: NEW FORMULATION needed. Applicant in NEGOTIATIONS with FDA

Comments (if any): 5/3/01: The firm has previously notified the Agency of their intent to pursue pediatric exclusivity. The Agency issued a letter on August 8, 2000 informing the firm that the Agency needed to collect more data to determine the types of necessary pediatric studies. Therefore, we are deferring submission of their pediatric studies under the rule. We are asking the firm to re-evaluate available information on this drug and the disease in children.

Ranges for This Indication

Lower Range	Upper Range	Status	Date
0 months	18 years	Deferred	6/1/03

Comments: 5/3/01: same comments as above.

This page was last edited on 5/3/01

/S/

Signature

5/3/01

Date

19.2 Pediatric Labeling

Pursuant to 21 CFR 314.55 (c)(2), TAP Pharmaceutical Products Inc. is requesting a waiver of the requirements of 314.55 (a) for pediatric use information for this submission. This New Drug Application (NDA) describes a new oral dosage form for lansoprazole, PREVACID® Sachet for Suspension. This NDA does not seek a new indication. Therefore, TAP respectfully requests a waiver of the requirement for pediatric use information for this NDA.

DEBARMENT CERTIFICATION

I hereby certify that TAP Pharmaceutical Products Inc. did not and will not use in any capacity the services of any person debarred under subsections (a) or (b) [section 306(a) or (b)] in connection with this application (NDA 21-281).

Nancy Lukasik

Nancy Lukasik
Clinical Reasearch Manager
TAP Pharmaceutical Products Inc.

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 21281/000
Stamp: 03-JUL-2000
Regulatory Due: 03-MAY-2001
Applicant: TAP PHARM
, ,
3S
Priority: 180
Org Code:

Action Goal:
District Goal: 04-MAR-2001
Brand Name: LANSOPRAZOLE FOR SUSPENSION
Estab. Name:
Generic Name: LANSOPRAZOLE FOR SUSPENSION

Dosage Form: (FOR ORAL SUSPENSION)
Strength: 15 & 30MG SACHET/DOSE

Application Comment: LANSOPRAZOLE ENTERIC COATED GRANULES ARE MANUFACTURED BY [redacted] AND SHIPPED IN BULK TO [redacted] THE INACTIVE GRANULES WHICH ARE COMPRISED OF THICKENING, SWEETENING, COLORING AND FLAVORING AGENTS ARE MANUFACTURED AT [redacted] WHICH ALSO MANUFACTURES THE 15 AND 30 MG UNIT DOSE SACHETS (LANSOPRAZOLE GRANULES AND INACTIVE GRANULES) OF PREVACID SACHET FOR SUSPENSION. HYD ([redacted] NDA 20-406) HAS BEEN DESIGNATED A STARTING MATERIAL BY TAP. ADDITIONAL STARTING MATERIAL MANUFACTURER OF HYD (NDA 20-406/SCM-019) IS [redacted], 3-11, [redacted] (on 10-JAN-2001 by J. SIECZKOWSKI (HFD-180) 301-827-7310)

FDA Contacts:

C. PERRY	(HFD-180)	301-827-7310 ,	Project Manager
J. SIECZKOWSKI	(HFD-180)	301-827-7310 ,	Review Chemist
L. ZHOU	(HFD-150)	301-594-5765 ,	Team Leader

Overall Recommendation: ACCEPTABLE on 27-APR-2001 by M. GARCIA (HFD-322) 301-594-0095

Establishment: [redacted]

DMF No: [redacted] AADA:
Responsibilities: [redacted]
Profile: CSN OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	10-JAN-2001				SIECZKOWSK
OC RECOMMENDATION	11-JAN-2001			ACCEPTABLE BASED ON PROFILE	EGASM

Establishment: [redacted]

DMF No: AADA:
Responsibilities: [redacted]
Profile: CSN OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	10-JAN-2001				SIECZKOWSK
SUBMITTED TO DO	11-JAN-2001	10D			EGASM
DO RECOMMENDATION	16-JAN-2001			ACCEPTABLE BASED ON FILE REVIEW	EGASM
BASED ON EI OF 6/15/99					
OC RECOMMENDATION	17-JAN-2001			ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

Establishment: [redacted]

[redacted]

DMF No: AADA:
Responsibilities: [redacted]
Profile: POW OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-AUG-2000				SIECZKOWSK
SUBMITTED TO DO	15-AUG-2000	GMP			EGASM
ASSIGNED INSPECTION	24-AUG-2000	GMP			EGASM
INSPECTION SCHEDULED	09-SEP-2000		22-SEP-2000		IRIVERA
INSPECTION PERFORMED	12-OCT-2000		20-SEP-2000		EGASM
THIS PRODUCT RECOMMENDED NAI					
DO RECOMMENDATION	27-OCT-2000			ACCEPTABLE	EGASM
				INSPECTION	
OC RECOMMENDATION	27-OCT-2000			ACCEPTABLE	EGASM
				DISTRICT RECOMMENDATION	
SUBMITTED TO OC	10-JAN-2001				SIECZKOWSK
SUBMITTED TO DO	11-JAN-2001	10D			EGASM
DO RECOMMENDATION	16-JAN-2001			ACCEPTABLE	EGASM
				BASED ON FILE REVIEW	
BASED ON EI OF 9/20/00					
OC RECOMMENDATION	17-JAN-2001			ACCEPTABLE	EGASM
				DISTRICT RECOMMENDATION	

Establishment: [redacted]

[redacted]

DMF No: AADA:
Responsibilities: [redacted]
Profile: CSN OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-AUG-2000				SIECZKOWSK
SUBMITTED TO DO	15-AUG-2000	GMP			EGASM
ASSIGNED INSPECTION	24-AUG-2000	GMP			EGASM
INSPECTION SCHEDULED	18-DEC-2000		09-FEB-2001		IRIVERA
SUBMITTED TO OC	10-JAN-2001				SIECZKOWSK
SUBMITTED TO DO	11-JAN-2001	GMP			EGASM
ASSIGNED INSPECTION	16-JAN-2001	GMP			EGASM
INSPECTION SCHEDULED	13-FEB-2001		09-FEB-2001		EGASM
INSPECTION PERFORMED	13-FEB-2001		09-FEB-2001		EGASM
APPROVAL IF FIRM RESPONSE IS ADEQUATE					
DO RECOMMENDATION	27-APR-2001			ACCEPTABLE	EGASM
				INSPECTION	
OC RECOMMENDATION	27-APR-2001			ACCEPTABLE	EGASM
				DISTRICT RECOMMENDATION	

Establishment: [redacted]

[redacted]

DMF No: AADA:
Responsibilities: [redacted]
Profile: CRU OAI Status: NONE

Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	15-AUG-2000				SIECZKOWSK
SUBMITTED TO DO	15-AUG-2000	10D			EGASM
ASSIGNED INSPECTION '	24-AUG-2000	GMP			EGASM
INSPECTION SCHEDULED	18-DEC-2000		06-FEB-2001		IRIVERA
SUBMITTED TO OC	10-JAN-2001				SIECZKOWSK
SUBMITTED TO DO	11-JAN-2001	GMP			EGASM
ASSIGNED INSPECTION '	16-JAN-2001	GMP			EGASM
INSPECTION SCHEDULED	13-FEB-2001		05-FEB-2001	-	EGASM
INSPECTION PERFORMED	13-FEB-2001		05-FEB-2001	-	EGASM
DO RECOMMENDATION	27-APR-2001			ACCEPTABLE	EGASM
OC RECOMMENDATION	27-APR-2001			INSPECTION ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

APPEARS THIS WAY
ON ORIGINAL